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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,735	11/17/2003	Robert Eugene Handfield JR.	PC23270A	4671

23913 7590 11/01/2006

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EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,735	HANDFIELD ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

- ✓ A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3, and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

The Status of Claims

Claims 1,3,5-17 are pending.

Claims 1,3,5-17 are rejected.

Claim Objections

The Objection of Claims 11 , 15, and 17 are withdrawn due to the modification of the claims in the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 3 and 5-9 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the cancellation of the claims in the amendment.

Art Unit: 1625

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1, 3, 6-9, 11-13, 15-17 under 35 U.S.C. 102(b) as being anticipated clearly by Singer (US2003/0060624 A)

The rejection of Claims 1, 3, 6-9, 11-13, 15-17 under 35 U.S.C. 102(b) as being anticipated clearly by Singer (US2003/0060624 A) has been maintained with the reasons of record on 3/21/06.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 1,3,5-17 under 35 U.S.C. 103(a) as being unpatentable over Singer (US2003/0060624 A).

Art Unit: 1625

The rejection of Claims 1,3,5-17 under 35 U.S.C. 103(a) as being unpatentable over Singer (US2003/0060624 A) has been maintained with the reasons of record on 3/21/06.

Applicants' Argument

Applicants argue the following issues:

- a. the sodium t-butoxide is used in the step 1 coupling reaction of the cited reference, whereas the ammonium hydroxide is used in the isolation after the step 2 reaction in the instant application.
- b. the distillation step is critical to controlling the stability, integrity, and purity of the product.
- c. The lack of using the s\distillation creates low yields, a production of messy gummy products.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the first, second, and third argument, the Examiner has noted applicants' arguments. However, a close inspection of the claim 1 does not provide any differences in using a particular type of base; furthermore, it does not require any special need for employment of distillation technique either. Also, the claims are not directed to the process of producing the high yield or the purity of the product, but it is directed to the improved process for preparing a compound of formula I.

Art Unit: 1625

Thus, from the above, with respect to the removal of the solvent by the distillation, it is well-known in the art that the distillation process is a common practice in any organic synthesis. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to use the distillation process in the prior art process so as to remove the solvent in the reaction medium rapidly as possible. This is because the skilled artisan in the art would expect such a manipulation to be feasible and successful since its application is well-known in the art.

Moreover, regarding the use of ammonium hydroxide as a base in the example, the prior art does mention that the reaction with alkali or alkaline earth metal or ammonium hydroxide or carbonate is generally in an aqueous alcohol or tetrahydrofuran at a temperature from room temperature to 70⁰ C. (see col. 17, lines 8-12); the base can be selected from the group of sodium carbonate, sodium t-butoxide in a solvent such as tetrahydrofuran (see col. 11, paragraph #0129, lines 14-20). From these teachings, there is a teaching of equivalence between ammonium hydroxide and sodium t-butoxide as the base in the process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to use ammonium hydroxide as an alternative base. This is because the skilled artisan in the art would expect such a modification to be feasible and successful as guidance shown in the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Taylor Victor Oh, MSD, LAC
Primary Examiner
Art Unit : 1625

10/29/06